IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

IN RE: ETHICON INC.
PELVIC REPAIR SYSTEMS
PRODUCT LIABILITY LITIGATION MDL No. 2327

THIS DOCUMENT RELATES TO:

Cases Identified in the Exhibit
Attached Hereto

MEMORANDUM OPINION AND ORDER
(*Daubert* Motion re: Dr. Cynthia Bergmann)

Pending before the court is the Motion to Exclude Certain Opinion and Testimony of Dr. Cynthia Bergmann [ECF No. 2046] filed by the plaintiffs. The Motion is now ripe for consideration because briefing is complete.

I. Background

This case resides in one of seven MDLs assigned to me by the Judicial Panel on Multidistrict Litigation concerning the use of transvaginal surgical mesh to treat pelvic organ prolapse ("POP") and stress urinary incontinence ("SUI"). In the seven MDLs, there are more than 75,000 cases currently pending, approximately 30,000 of which are in this MDL, which involves defendants Johnson & Johnson and Ethicon, Inc. (collectively "Ethicon"), among others.

In this MDL, the court's tasks include "resolv[ing] pretrial issues in a timely and expeditious manner" and "resolv[ing] important evidentiary disputes." Barbara J. Rothstein & Catherine R. Borden, Fed. Judicial Ctr., *Managing Multidistrict*

Litigation in Products Liability Cases 3 (2011). To handle motions to exclude or to limit expert testimony pursuant to *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), the court developed a specific procedure. In Pretrial Order ("PTO") No. 217, the court instructed the parties to file only one *Daubert* motion per challenged expert, to file each motion in the main MDL—as opposed to the individual member cases—and to identify which cases would be affected by the motion. PTO No. 217, at 4.[1]

II. Preliminary Matters

Before plunging into the heart of the Motion, a few preliminary matters need to be addressed.

I am compelled to comment on the parties' misuse of my previous *Daubert* rulings on several of the experts offered in this case. *See generally Sanchez v. Bos. Sci. Corp.*, No. 2:12-cv-05762, 2014 WL 4851989 (S.D. W. Va. Sept. 29, 2014); *Tyree v. Bos. Sci. Corp.*, 54 F. Supp. 3d 501 (S.D. W. Va. 2014); *Eghnayem v. Bos. Sci. Corp.*, 57 F. Supp. 3d 658 (S.D. W. Va. 2014). The parties have, for the most part, structured their *Daubert* arguments as a response to these prior rulings, rather than an autonomous challenge to or defense of expert testimony based on its reliability and relevance. In other words, the parties have comparatively examined expert testimony and have largely overlooked *Daubert*'s core considerations for assessing expert

[1] The plaintiffs identified the Wave 1 cases affected by this Motion in their attached Exhibit A [ECF No. 2046-1], which the court has attached to this Memorandum Opinion and Order. At the time of transfer or remand, the parties will be required to designate relevant pleadings from MDL 2327, including the motion, supporting memorandum, response, reply, and exhibits referenced herein.

testimony. Although I recognize the tendency of my prior evidentiary determinations to influence subsequent motions practice, counsels' expectations that I align with these previous rulings when faced with a different record are misplaced, especially when an expert has issued new reports and given additional deposition testimony.

Mindful of my role as gatekeeper for the admission of expert testimony, as well as my duty to "respect[ ] the individuality" of each MDL case, *see In re Phenylpropanolamine Prods. Liab. Litig.*, 460 F.3d 1217, 1231 (9th Cir. 2006), I refuse to credit *Daubert* arguments that simply react to the court's rulings in *Sanchez* and its progeny. Indeed, I feel bound by these earlier cases only to the extent that the expert testimony and *Daubert* objections presented to the court then are identical to those presented now. Otherwise, I assess the parties' *Daubert* arguments anew. That is, in light of the particular expert testimony and objections currently before me, I assess "whether the reasoning or methodology underlying the testimony is scientifically valid" and "whether that reasoning or methodology properly can be applied to the facts in issue." *Daubert*, 509 U.S. at 592–93. Any departure from *Sanchez*, *Eghnayem*, or *Tyree* does not constitute a "reversal" of these decisions and is instead the expected result of the parties' submission of updated expert reports and new objections to the expert testimony contained therein.

Finally, I have attempted to resolve all possible disputes before transfer or remand, including those related to the admissibility of expert testimony pursuant to *Daubert*. Nevertheless, in some instances I face *Daubert* challenges where my interest in accuracy counsels reserving ruling until the reliability of the expert

testimony may be evaluated at trial. At trial, the expert testimony will be tested by precise questions asked and answered. The alternative of live *Daubert* hearings is impossible before transfer or remand because of the numerosity of such motions in these seven related MDLs. As these MDLs have grown and the expert testimony has multiplied, I have become convinced that the critical gatekeeping function permitting or denying expert testimony on decisive issues in these cases is best made with a live expert on the witness stand subject to vigorous examination.

In the course of examining a multitude of these very similar cases involving the same fields of expertise, I have faced irreconcilably divergent expert testimony offered by witnesses with impeccable credentials, suggesting, to me, an unreasonable risk of unreliability. The danger—and to my jaded eye, the near certainty—of the admission of "junk science" looms large in this mass litigation.

The parties regularly present out-of-context statements, after-the-fact rationalizations of expert testimony, and incomplete deposition transcripts. This, combined with the above-described practice of recycling expert testimony, objections, and the court's prior rulings, creates the perfect storm of obfuscation. Where further clarity is necessary, I believe it can only be achieved through live witness testimony—not briefing—and I will therefore reserve ruling until the expert testimony can be evaluated firsthand.

III. Legal Standard

By now, the parties should be intimately familiar with Rule 702 of the Federal Rules of Evidence and *Daubert*, so the court will not linger for long on these

standards.

Expert testimony is admissible if the expert is qualified and if his or her expert testimony is reliable and relevant. Fed. R. Evid. 702; *see also Daubert*, 509 U.S. at 597. An expert may be qualified to offer expert testimony based on his or her "knowledge, skill, experience, training, or education." Fed. R. Evid. 702. Reliability may turn on the consideration of several factors:

> (1) whether a theory or technique can be or has been tested; (2) whether it has been subjected to peer review and publication; (3) whether a technique has a high known or potential rate of error and whether there are standards controlling its operation; and (4) whether the theory or technique enjoys general acceptance within a relevant scientific community.

Cooper v. Smith & Nephew, Inc., 259 F.3d 194, 199 (4th Cir. 2001) (citing *Daubert*, 509 U.S. at 592–94). But these factors are neither necessary to nor determinative of reliability in all cases; the inquiry is flexible and puts "principles and methodology" above conclusions and outcomes. *Daubert*, 509 U.S. at 595; *see also Kumho Tire Co. v. Carmichael*, 525 U.S. 137, 141, 150 (1999). Finally, and simply, relevance turns on whether the expert testimony relates to any issues in the case. *See, e.g.*, *Daubert*, 509 U.S. at 591–92 (discussing relevance and helpfulness).

At bottom, the court has broad discretion to determine whether expert testimony should be admitted or excluded. *Cooper*, 259 F.3d at 200.

IV. Discussion

Dr. Bergmann is board-certified in obstetrics and gynecology, and she is a fellow of the American College of Obstetricians and Gynecologists. She has used the

TVT sling in hundreds of surgical procedures.

a. Internal Documents

The plaintiffs seek to exclude Dr. Bergmann's reliance on any internal documents that she did not review prior to completing her expert report. The plaintiffs point out that Dr. Bergmann admitted during her deposition that she did not review certain Ethicon emails and other internal corporate documents. Dr. Bergmann does not appear to rely on the challenged internal documents in her report, and this issue arose out of the plaintiffs' counsel's own questioning. Interestingly, Ethicon asserts that Dr. Bergmann *should* be allowed to opine on documents that she did not rely on in forming her opinion and did not disclose to the plaintiffs. I will not permit Dr. Bergmann to rely on internal documents that she did not rely on in initially forming her opinions. These opinions are **EXCLUDED**.

b. Qualification to Offer Opinion Regarding Pubovaginal Slings

The plaintiffs assert that Dr. Bergmann is entirely unqualified to opine on complications and morbidity associated with pubovaginal sling procedures because she does not have any training or experience with pubovaginal slings. Dr. Bergmann is an experienced surgeon, and she has offered opinions—both in her report and her deposition—regarding multiple treatment options for SUI. Dr. Bergmann has demonstrated that she has the requite skill, knowledge, and experience regarding the various risks associated with various treatment options, and the fact that she does not use a specific treatment option is not dispositive. As a gynecologist and surgeon, Dr. Bergmann is sufficiently qualified to opine on risks and complications associated

with various treatment options about which she routinely discusses with her patients. The plaintiffs' Motion is **DENIED** on this point.

c. Qualification to Opine on Alternative Mesh Materials

The plaintiffs claim Dr. Bergmann is not qualified to offer expert testimony related to alternative mesh materials because, as the plaintiffs put it, "she does not know that the TVT device is made of Prolene mesh." Mem. Supp. Mot. 5. Clearly, Dr. Bergmann knows TVT is made of Prolene. *E.g.*, Report at 16 (discussing "[t]he Prolene mesh used in the TVT product"). The plaintiffs also claim Dr. Bergmann's deposition testimony that TVT and Gynemesh are different conflicts with her report. According to the plaintiffs, her report states that Gynemesh is an alternative material to Prolene. This argument rests on a misinterpretation of Dr. Bergmann's report as compared to her deposition testimony. Accordingly, the plaintiffs' Motion is **DENIED** on these points.[2]

d. Warnings

The plaintiffs claim Dr. Bergmann is not qualified to offer expert testimony about product warnings, which includes expert testimony about the adequacy of the relevant Instructions for Use ("IFU"). According to the plaintiffs, Dr. Bergmann is not an expert in the development of warnings labels and thus is not qualified to offer expert testimony about warnings. While an expert who is a urologist may testify about the specific risks of implanting mesh and whether those risks appeared on the

[2] In the final sentence of this section of their Motion, the plaintiffs claim Dr. Bergmann's expert testimony about alternative mesh materials is unreliable. This argument is identical to the qualifications challenge, and I reject it for the same reasons.

relevant IFU, the same expert must possess additional expertise to offer expert testimony about what information should or should not be included in an IFU. *Wise v. C. R. Bard, Inc.*, No. 2:12-cv-1378, 2015 WL 521202, at *14 (S.D. W. Va. Feb. 7, 2015). Dr. Bergmann does not possess the additional expertise to offer expert testimony about what an IFU should or should not include. Accordingly, Dr. Bergmann's expert testimony about these matters is **EXCLUDED**.

e. Properties

The plaintiffs seek exclusion of Dr. Bergmann's opinions regarding particle loss and degradation.

As to particle loss, the plaintiffs object to Dr. Bergmann's statement that in her experience with the TVT device, she has not seen any significant particle loss in her patients. The plaintiffs challenge the reliability of this opinion because the opinion allegedly conflicts with an Ethicon document stating particle loss occurs with the TVT device and Dr. Bergmann could not testify as to the Ethicon document and the definition of particle loss therein. I do not find that Dr. Bergmann's unfamiliarity with Ethicon's internal document on particle loss has any bearing on her reporting of her personal experience with particle loss. Accordingly, because the plaintiffs do not make any further arguments regarding the reliability of Dr. Bergmann's opinion on particle loss, the plaintiffs' Motion is **DENIED**.

As to degradation, the plaintiffs object to Dr. Bergmann's statement that she has not seen clinically significant degradation of TVT mesh in her practice or described in the published literature. She concludes that "[i]f the TVT device

degraded as plaintiffs' witnesses claim, one would not see the excellent long-term efficacy and safety shown in the published medical literature." Bergmann Report 17 [ECF No. 2046-3]. The plaintiffs argue that these opinions are not reliable or scientifically sound.

On the one hand, Dr. Bergmann has based her opinion on her extensive clinical experience and a review of the medical and scientific literature, which, in the abstract, are reasonable bases on which to form an expert opinion. *See Kumho*, 526 U.S. at 156 ("[N]o one denies that an expert might draw a conclusion from a set of observations based on extensive and specialized experience.").

On the other hand, the court does not have enough information to judge the reliability or helpfulness of these particular clinical observations. *See* Fed. R. Evid. 702 advisory committee's note to 2000 amendment ("If the witness is relying solely or primarily on experience, then the witness must explain how that experience leads to the conclusion reached, why that experience is a sufficient basis for the opinion, and how that experience is reliably applied to the facts."). Perhaps Dr. Bergmann did not observe evidence of degradation because she was not looking. Or perhaps her method of identifying and tracking degradation is not scientifically sound. Additionally, although the expert report indicates Dr. Bergmann reviewed an extensive list of literature in forming her opinions generally, the court is not directed to specific support for the statements at issue or detail about Dr. Bergmann's methodology.

I am without sufficient information at this time to draw the fine line between reliable and unreliable expert testimony on mesh degradation based primarily on a

doctor's clinical experiences *not* observing something. Accordingly, I **RESERVE** ruling until further testimony may be offered and evaluated firsthand at trial.

f. Self-Created Table

The plaintiffs argue that any information contained in Table 1 of Dr. Bergmann's report should be excluded because the information is unreliable. Dr. Bergmann created the table to summarize her review of various studies comparing different devices and procedures. Ethicon argues that there is no key or legend on the table, and the studies Dr. Bergmann includes examine devices other than the TVT—allegedly making parts of the table irrelevant. Dr. Bergmann discussed her methodology and her system for interpreting the table in her deposition. However, I am currently without enough information to understand the extent of her review of the scientific literature and the reliability of her rating system. For example, Dr. Bergmann found the studies she relies on by performing Google searches. Accordingly, I will **RESERVE** ruling on the reliability and relevance of Table 1, which is included in Dr. Bergmann's report.

V. Recurring Issues

Many of the *Daubert* motions filed in this MDL raise the same or similar objections.

One particular issue has been a staple in this litigation, so I find it best to discuss it in connection with every expert. A number of the *Daubert* motions seek to exclude FDA testimony and other regulatory or industry standards testimony. To the extent this Motion raises these issues it is **GRANTED in part** and **RESERVED in**

part as described below.

I have repeatedly excluded evidence regarding the FDA's section 510(k) clearance process in these MDLs, and will continue to do so in these cases, a position that has been affirmed by the Fourth Circuit. *In re C. R. Bard, Inc.*, 81 F.3d 913, 921–23 (4th Cir. 2016) (upholding the determination that the probative value of evidence related to section 510(k) was substantially outweighed by its possible prejudicial impact under Rule 403). Because the section 510(k) clearance process does not speak directly to safety and efficacy, it is of negligible probative value. *See In re C. R. Bard*, 81 F.3d at 920 ("[T]he clear weight of persuasive and controlling authority favors a finding that the 510(k) procedure is of little or no evidentiary value."). Delving into complex and lengthy testimony about regulatory compliance could inflate the perceived importance of compliance and lead jurors "to erroneously conclude that regulatory compliance proved safety." *Id.* at 922. Accordingly, expert testimony related to the section 510(k) process, including subsequent enforcement actions and discussion of the information Ethicon did or did not submit in its section 510(k) application, is **EXCLUDED**. For the same reasons, opinions about Ethicon's compliance with or violation of the FDA's labeling and adverse event reporting regulations are **EXCLUDED**. In addition to representing inappropriate legal conclusions, such testimony is not helpful to the jury in determining the facts at issue in these cases and runs the risk of misleading the jury and confusing the issues. Insofar as this Motion challenges the FDA-related testimony discussed here, the Motion is **GRANTED**.

A number of experts also seek to opine on Ethicon's compliance with design control and risk management standards. Some of this testimony involves the FDA's quality systems regulations, and some—likely in an attempt to sidestep my anticipated prohibition on FDA testimony—involve foreign regulations and international standards. I find all of this proposed testimony of dubious relevance. Although these standards relate to how a manufacturer should structure and document risk assessment, the standards do not appear to mandate any particular design feature or prescribe the actual balance that must be struck in weighing a product's risk and utility. Nor is it clear that the European and other international standards discussed had any bearing on the U.S. medical device industry when the device in question was being designed.

Nevertheless, because the nuances of products liability law vary by state, I will refrain from issuing a blanket exclusion on design process and control standards testimony, whether rooted in the FDA or otherwise. Each standard must be assessed for its applicability to the safety questions at issue in this litigation, consistent with state law. I am without sufficient information to make these findings at this time. Accordingly, I **RESERVE** ruling on such matters until a hearing, where the trial judge will have additional context to carefully evaluate the relevance and potential prejudicial impact of specific testimony.

Similarly, I doubt the relevance of testimony on the adequacy of Ethicon's clinical testing and research, physician outreach, or particular product development procedures and assessments otherwise not encompassed by the above discussion.

Again, such matters seem to say very little about the state of the product itself (i.e., whether or not it was defective) when it went on the market. But because the scope of relevant testimony may vary according to differences in state products liability law, I **RESERVE** ruling on such matters until they may be evaluated in proper context at a hearing before the trial court before or at trial.

Additional—and more broad—matters also warrant mention. While some of these concerns may not apply to this particular expert, these concerns are raised so frequently that they are worth discussing here.

First, many of the motions seek to exclude state-of-mind and legal-conclusion expert testimony. Throughout these MDLs, the court has prohibited the parties from using experts to usurp the jury's fact-finding function by allowing testimony of this type, and I do the same here. *E.g.*, *In re C. R. Bard, Inc.*, 948 F. Supp. 2d 589, 611 (S.D. W. Va. 2013); *see also, e.g.*, *United States v. McIver*, 470 F.3d 550, 562 (4th Cir. 2006) ("[O]pinion testimony that states a legal standard or draws a legal conclusion by applying law to the facts is generally inadmissible."); *In re Rezulin Prods. Liab. Litig.*, 309 F. Supp. 2d 531, 546 (S.D.N.Y. 2004) ("Inferences about the intent and motive of parties or others lie outside the bounds of expert testimony."). Additionally, an expert may not offer expert testimony using "legal terms of art," such as "defective," "unreasonably dangerous," or "proximate cause." *See Perez v. Townsend Eng'g Co.*, 562 F. Supp. 2d 647, 652 (M.D. Pa. 2008).

Second, and on a related note, many of the motions seek to prohibit an expert from parroting facts found in corporate documents and the like. I caution the parties

against introducing corporate evidence through expert witnesses. Although an expert may testify about his or her review of internal corporate documents solely for the purpose of explaining the basis for his or her expert opinions—assuming the expert opinions are otherwise admissible—he or she may not offer testimony that is solely a conduit for corporate information.

Third, many of the motions also ask the court to require an expert to offer testimony consistent with that expert's deposition or report or the like. The court will not force an expert to testify one way or another. To the extent an expert offers inconsistent testimony, the matter is more appropriately handled via cross-examination or impeachment as appropriate and as provided by the Federal Rules of Evidence.

Fourth, in these *Daubert* motions, the parties have addressed tertiary evidentiary matters like whether certain statements should be excluded as hearsay. The court will not exclude an expert simply because a statement he or she discussed may constitute hearsay. *Cf. Daubert*, 509 U.S. at 595. Hearsay objections are more appropriately raised at trial.

Finally, in some of the *Daubert* motions, without identifying the specific expert testimony to be excluded, the parties ask the court to prevent experts from offering testimony the expert is not qualified to offer. I will not make speculative or advisory rulings. I decline to exclude testimony where the party seeking exclusion does not provide specific content or context.

VI. Conclusion

The court **DENIES in part**, **GRANTS in part**, and **RESERVES in part** the Motion Exclude Certain Opinions and Testimony of Dr. Cynthia Bergmann [ECF No. 2046].

The court **DIRECTS** the Clerk to file a copy of this Memorandum Opinion and Order in 2:12-md-2327 and in the Ethicon Wave 1 cases identified in the Exhibit attached hereto.

ENTER: August 31, 2016

JOSEPH R. GOODWIN
UNITED STATES DISTRICT JUDGE

EXHIBIT A- Bergmann

CASE STYLE	CASE NUMBER
Constance Daino v. Ethicon Inc., et al.	Case No. 2:12-cv-01145
Rebekah Bartlett ~~(Pratt)~~ v. Ethicon Inc., et al.	Case No. 2:12-cv-01273
Donna Hankins v. Ethicon Inc., et al.	Case No. 2:12-cv-01011